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DEC 13 2000

510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Submitter:	William Skremsky CTI PET Systems, Inc. 810 Innovation Drive Knoxville, TN 37932
Telephone No:	(865) 218-2522
Fax No:	(865) 218-3000
Date of preparation:	October 13, 2000

Identification of the Product

Device Proprietary Name:	ECAT ART-LSO PET Scanner
Common Name:	Positron Emission Tomography (PET) Scanner
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT ART PET System	CTI PET Systems (CPS)	K940478

Device Description

The proposed ECAT ART-LSO PET tomograph is a whole body positron emission tomography (PET) system providing 3D volume measurements of metabolic (molecular) and physiologic processes. The ECAT ART-LSO PET tomograph is a modified version of the currently marketed ECAT ART PET scanner (K940478) with changes involving the detector assembly. The ECAT ART-LSO PET tomograph will use a new PET scintillator, lutetium oxyorthosilicate (LSO).

The use of LSO will provide improved count rate performance and faster transmission and emission scanning as compared to the currently marketed ECAT ART PET tomograph which utilizes bismuth germanate (BGO).

Like the original ECAT ART, the ECAT ART-LSO is also a partial ring tomograph having two opposed banks of detectors rotating continuously around the field of view, rather than complete rings of stationary detectors. The number of detectors used and their configuration in the ECAT ART-LSO is identical to that of the original ECAT ART scanner.

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Simultaneous 3D acquisition, image reconstruction, processing, and data analysis can be performed to generate high patient throughput and prompt results using the most recent released version of ECAT System Software. ECAT Software is used in the acquisition, reconstruction, archiving, display, and processing of data acquired from ECAT positron emission tomography scanners. In addition, the ECAT Software controls the motions of the patient handling system and transmission sources.

Indications for Use

Siemens/CPS ECAT positron emission tomography scanners are intended to be utilized by appropriately trained health care professionals to image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body.

Comparison with Predicate Devices

The ECAT ART-LSO PET tomograph is similar in design and function to the currently marketed ECAT ART Scanner (K940478) with changes involving the detector assembly. The ECAT ART-LSO PET scanner will use LSO as its detector material which will provide improved count rate performance and faster transmission and emission scanning as compared to the ECAT ART PET tomograph which utilizes bismuth germanate (BGO). The system is intended to be used in fixed as well as mobile operations.

The ART-LSO also incorporates several improvements from the original ECAT ART. These improvements include a lighter and more rigid gantry frame, a more reliable rotational bearing assembly, an improved slip ring assembly, and a more reliable rotation drive motor and motor controller. Other than the detectors, the ART-LSO PET system will consist of the same components as those used for the ECAT ART including the gantry, an integrated workstation, 3D Advanced Computational System (ACS II) and Patient Handling System.

ECAT ART-LSO will use the most recent released version of ECAT System Software. Use of the LSO detectors will require minor software changes including a modification to the system time alignment routine and a minimal change to the reconstruction software. These software changes will be transparent to the system user and, therefore, no changes to the software operating instructions are anticipated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Mr. William Skremsky
Regulatory Affairs Specialist
CTI PET Systems, Inc.
810 Innovation Drive
KNOXVILLE TN 37932

Re: K003241
ECAT PET Scanner
Dated: October 13, 2000
Received: October 17, 2000
Regulatory Class: II
21 CFR §892.1200/Procode: 90 KPS

Dear Mr. Skremsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003241

Device Name: ECAT ART-LSO PET Scanner

Indications for Use:

Siemens/CPS ECAT positron emission tomography (PET) scanners are intended to be utilized by appropriately trained health care professionals to detect the location and distribution of injected positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003241